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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/124,280	07/29/1998	MASSIMO PORRO	576008	6533

7590 04/24/2002

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/124,280	PORRO, MASSIMO	
	<b>Examiner</b>	<b>Art Unit</b>	
	N. M. Minnifield	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-17, 19-35 and 37-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35, 37-50, 52, 53 and 56 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 19-34, 51, 54, 55, 57-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's amendment filed February 8, 2002 is acknowledged and has been entered. Claims 25, 42-46, 49, 50 and 55 have been amended. New claims 63 and 64 have been added. Claims 1-8, 10-17, 19-35 and 37-64 are now pending in the present application. All rejections have been withdrawn in view of Applicant's amendment, with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-8, 10-17, 19-34, 51, 54, 55 and 57-64 under 35 U.S.C. 102(b) as being anticipated by Porro is maintained.

Applicant's arguments filed August 22, 2000 have been fully considered but they are not persuasive. Applicant's arguments have been addressed previously. Further, the claims do not recite "stoichiometric excess of peptide relative to the lipid moiety". However, the Examiner is not suggesting addition of this limitation to the claims.

Applicant's arguments filed May 8, 2001 have been fully considered but they are not persuasive. Applicant's arguments have been addressed previously. Applicant has argued that the Porro patent does not disclosed using a stoichiometric excess of the peptide relative to LPS. However, the determination of optimum concentrations of reactants or disclosed using a stoichiometric excess of the peptide relative to LPS using in within the level of ordinary skill in the art. See In re Kronig, 190 USPQ 425.

Applicant's arguments filed February 8, 2002 have been fully considered but they are not found persuasive. Applicant states that the prior art does not teach using a stoichiometric excess of peptide relative to the lipid moiety and that the method Applicant uses to make the vaccine is not disclosed in the prior art. However, the claimed invention is a vaccine comprising LPS and a peptide which the prior art discloses. Applicant appears to be arguing a process limitation and novel process or improved methods of preparing the vaccine, not the vaccine composition itself. The concept of using a stoichiometric excess of the peptide relative to LPS is viewed as a process limitation. Further, the specification states that stoichiometric excess is necessary to significantly stabilize the LPS-peptide complex from the likely antagonistic activity of natural LPS-receptor proteins present on specialized cells of the immune system which bear amino acid sequences similar to that of the peptides used in the invention. (Specification, p. 6). This is a part of the method of preparing the vaccine, a process limitation.

It is also noted that Porro discloses the use of LPS from any gram-negative bacteria since septic shock is caused by the release of endotoxin or LPS by gram-negative bacteria.

4. Claims 35, 37-50, 52, 53 and 56 appear to be free of the prior art since the prior art does not disclose a vaccine comprising LPS with the specifically claimed peptides as set forth in claims 35, 37-50, 52, 53 and 56.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the

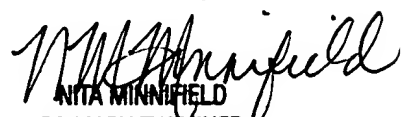
advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nita M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
NITA MINNIFIELD  
PRIMARY EXAMINER  
AU. 1645  
4-16-02